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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/936,786

02/08/2002

Eugene O. Major

2370-67

9275

23117

7590

10/14/2005

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,786

Applicant(s)

MAJOR ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 14-25 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 13, 26-28, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/6/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Arguments

1. The amendment filed on 8/003/05 has been entered.
2. Applicant's arguments filed 8/03/05 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This application contains claims 5-11, 14-25, 29-32 drawn to an invention nonelected with traverse in Paper No. 10/22/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
5. Claims 1-4, 12-13, 26-28 & 33-34 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 & 16 of U.S. Patent No. 5,753,491, for the reasons made of record in Paper No: 1/31/05.

In contrast to Applicants' assertions on page 7 of the response, the instant claims recite open claim language, and further encompass immortal human multipotent CNS neural stem cells, as claimed in '491. In addition, Shidler et al. (IDS Ref #PR) teach that only differentiating

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neurons bind to ChTx. Therefore, multipotent neural stem cells inherently are ChTx negative, in contrast to Applicants' assertions.

6. Claims 1-4, 12-13, 26-28 & 33-34 stand rejected under 35 U.S.C. 102(e) as being anticipated by Major et al (U.S. Patent 5,753,491; IDS Ref #2), for the reason made of record in Paper NO: 1/31/05, and as follows.

In contrast to Applicants' assertions on page 7 of the response, the instant claims recite open claim language, which therefore encompass Major's immortal human multipotent CNS neural stem cell line, because similar methods are used to generate both Major's and the multipotent immortal CNS stem cell lines of the instant invention; thereby, reasonably also being ChTx negative; absent evidence to the contrary. *In arguendo*, Shidler et al. (IDS Ref #PR) teach that only differentiating neurons bind to ChTx. Therefore, multipotent neural stem cells are inherently ChTX negative, by definition.

In summary, Major et al disclose isolated, immortalized CNS human fetal neuro-derived cell lines, which "generally produce progenitor neuronal and glial cells" (e.g., column 7, lines 22-37); thereby, being multipotent, by definition (i.e., as it relates to claims 1-3, 12 & 33). Cells derived from SVG cells are also described by Major (e. g., column 4, lines 66 - column 5, line 1; column 7, lines 57-65), which further appear identical to those cells (i.e., multipotent cells) described on pgs 3 & 15-17 of the instant specification (i.e., as it also relates to claims 1-3, 12 and 33). In that all of these cells described by Major et al reasonably appear identical to the alternative names of "NG1, NG2 and NG3" cells recited in claim 13, and inherently express markers that uniquely define what constitutes a multipotent stem cell, the limitations of claims 4 and 13 are met; absent evidence to the contrary. Finally, in that the process of producing

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multipotent neural stem cells does not materially change the multipotent neural stem cell product produced, the limitations of claims 26-28 and 34 are anticipated.

7. Claims 1-4, 12-13, 26-28 and 33-34 stand rejected under 35 U.S.C. 102(e) as being anticipated by Weiss et al (U.S. Patent 5,750,376; IDS Ref #3), for the reason made of record in Paper NO: 1/31/05, and as follows.

In contrast to Applicants' assertions on page 7 of the response, the instant claims recite open claim language, which therefore encompass Weiss' human multipotent CNS neural stem cell lines, and because no product-by-process steps have been used to generate the multipotent immortal cell lines of the instant invention that separate ChTx negative cells from putative ChTx positive cells. *In arguendo*, Shidler et al. (IDS Ref #PR) teach that only differentiating neurons bind to ChTx. Therefore, Weiss' multipotent CNS neural stem cells/neurospheres are inherently ChTx negative, by definition.

In summary, Weiss et al disclose isolated human CNS multipotent neural stem cell lines (i.e., neurospheres; as it relates to claims 33-34), which are clonally-derived/ "immortalized" and have the "potential to differentiate toward a neuronal cell or a glial cell" (e.g., column 11, lines 49-56) columns 13, 17- 18, 21-22, 36 and 48; as it relates to claims 1-3 and 12). In that the multipotent stem cells described by Weiss et al reasonably appear identical to the alternative names of "NG1, NG2 and NG3" cells recited in claim 13, and inherently express markers that uniquely define what constitutes a multipotent neural stem cell (e. g., column 56), the limitations of claims 4 and 13 are met; absent evidence to the contrary. Finally, in that the process of

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producing multipotent neural stem cells does not materially change the multipotent neural stem cell product produced, the limitations of claims 26-28 and 34 are anticipated.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
October 11, 2005

ROBERT C. HAYES, PH.D.
Primary **PATENT EXAMINER**